



## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable) – Pepaxto Utilization Review Medical Policy

- Pepaxto® (melphalan flufenamide intravenous infusion – Oncopeptides)

**REVIEW DATE:** 03/10/2021

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### OVERVIEW

Pepaxto, an alkylating drug, is indicated in combination with dexamethasone, for treatment of adults with relapsed or refractory **multiple myeloma**, who have received at least four prior lines of therapy, and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Pepaxto is not recommended for use as a conditioning regimen for transplant.

### Guidelines

Pepaxto is not addressed in current guidelines from the National Comprehensive Cancer Network (NCCN).<sup>2</sup> NCCN guidelines for multiple myeloma (version 4.2021 – December 10, 2020) address the diagnosis, treatment, and follow-up for patients with multiple myeloma.<sup>2,3</sup> Although Pepaxto is not addressed, other formulations of melphalan (melphalan, melphalan hydrochloride) are addressed in the guidelines. For non-transplant candidates, melphalan in combination with Darzalex/bortezomib/prednisone is among the regimens for primary therapy.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Pepaxto. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Pepaxto as well as the monitoring required for adverse events and long-term efficacy, approval requires Pepaxto to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pepaxto is recommended in those who meet one of the following criteria:

#### FDA-Approved Indications

1. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) The medication will be used in combination with dexamethasone; AND
  - C) Patient has tried at least four regimens for multiple myeloma; AND
  - D) Among the previous therapies tried, the patient has received at least one drug from each of the following classes (i, ii, and iii):
    - i. Proteasome inhibitor; AND

Note: Examples include Velcade (bortezomib injection), Kyprolis (carfilzomib infusion), Ninlaro (ixazomib capsules).

ii. Immunomodulatory drug; AND

Note: Examples include Revlimid (lenalidomide capsules), Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).

iii. Anti-CD38 monoclonal antibody; AND

Note: For example, Darzalex (daratumumab infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc infusion).

E) The medication is prescribed by or in consultation with an oncologist.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pepaxto is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Pepaxto [prescribing information]. Waltham, MA: Oncoceptides; February 2020.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 4, 2021. Search term: Papexto, melphalan.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 3.2020 – March 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 18, 2020.

## HISTORY

Type of Revision	Summary of Changes	Review Date
New policy	--	03/10/2021

## PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaaajila gargaarsa afaanij, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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ማስታወሻ: የሚገኙት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግኝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1.800.940.5049 (መለስማት ለተሳናቸው፡ 763.847.4013)፡

ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျီၣ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

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ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

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If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Insurance Company  
PO Box 59212  
Minneapolis, MN 55459-0212  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

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